SUBJECT: Data Operations for Data and Safety Monitoring Board Review under the caBIG™ Program	SOP No.: CR-010
	Version No.: 1.0
	Effective Date: 12/11/2006
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Standard Operating Procedure –

Data Operations for Data and Safety Monitoring Board Review

This cover sheet controls the layout and components of the entire document.

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Effective Date: December 11, 2006

Department Approval:

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Chief Operating Officer, NCICB

QA Approval:

George Komatsoulis

Director of Quality Assurance

Note: This document will be issued for training at the Issue Date. The document will become available for use to trained personnel on the Effective Date. Before using this document, make sure it is the latest revision as posted on the caBIG™ website.

Revision History

Revision	Date	Author	Change Reference	Reason for Change
1.0	November 22, 2005	SOP WG Review	All pages	Document Creation
1.0	December 13, 2005	SOP WG Approval	All pages	Document Creation
1.0	January 10, 2006	BP SIG Approval	All pages	Document Creation
1.0	October 30, 2006	BP SIG/SOP WG	All pages	Initial release.

Standard Operating Procedure

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1. Purpose

This SOP outlines the requirements for and responsibilities of clinical data management and the clinical study team for responding to inquiries from the Data and Safety Monitoring Board (DSMB). This SOP is in line with FDA requirements and the consolidated GCP guidance document ICH E6.

2. Scope

This SOP applies to the establishment and roles of the clinical data management and the clinical study team to support requests by the DSMB in support of clinical research trials under the caBIG™ Program at the National Cancer Institute (NCI).

3. Requirements

3.1 DSMB should review data only by masked study group or patient unless or until the DSMB determines that the identities of the group or the patient are required for their decision making.

3.2 All clinical research trials at the NCI are subject to review and governance by the DSMB.

3.3 All clinical research personnel conducting the clinical research trial will remain blinded during review by the DSMB, in accordance with protocol specifications.

4. References/Regulations/Guidelines

Section	SOP Number	Title
4.1	N/A	ICH E6: Good Clinical Practice: Consolidated Guidance
4.2	N/A	45 CFR Part 46: Protection of Human Subjects

5. Roles & Responsibilities

Role	Responsibility
DSMB	• Conduct periodic review of accumulating safety data to identify current and/or new patient safety issues. • Request from the Principal Investigator, clinical research trial data for review. • Provide feedback to the Principal Investigator on safety issue findings and/or recommendations.

Role	Responsibility
Principal Investigator	• Notify DSMB of all new safety information findings. • Transmit the final summary of DSMB findings and recommendations to the appropriate IRB in accordance with NIH Policies & Procedures. • Respond to all DSMB recommendations in writing in a timely manner.
Study Statistician	• Respond to requests from DSMB for clinical research trial data. • Provide blinded or unblinded data extractions as requested by the DSMB.
Clinical Study Team	• Respond to requests from DSMB for safety issues, as appropriate.

6. Attachments

This SOP will be used in conjunction with the following attachments. These attachments must be used by all clinical trial management system adopters and can be customized by individual research sites to accommodate format and content in accordance with local guidelines and/or requirements.

TITLE	DESCRIPTION
1) Procedure Description for Data Operations for Data and Safety Monitoring Board Review	This document provides instructions for the clinical research team's response to DSMB requests and it provides step-by-step guidance to assure that all requests are met, recorded and managed in a consistent manner.
2) Process Flow for Data Operations for Data and Safety Monitoring Board Review	This document graphically depicts the work flow activities, by role, that are performed in the process for responding to DSMB requests.